DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

September 8, 2014

Stryker IMT
Ms. Becky Ditty
Sr. Staff Regulatory Affairs Specialist
4100 E. Milham Ave.
Kalamazoo, MI 49001

Re: K141551
Trade/Device Name: Stryker PROFESS System
Regulation Number: 21 CFR 882.4560
Regulation Name: Ear, Nose, and Throat Stereotaxic Instrument
Regulatory Class: Class II
Product Code: PGW
Dated: June 10, 2014
Received: June 11, 2014

Dear Ms. Ditty:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

Device Name
Stryker PROFESS™ System

Indications for Use *(Describe)*
The Stryker PROFESS™ system is a navigation surgical software module that, when used with a specific Stryker computer workstation, is intended as an intraoperative guidance system to enable intranasal and sinus computer-assisted surgery. The system tracks and displays the intraoperative location of navigated surgical instruments relative to a CT image. The system can be used for intraoperative guidance where a reference to a rigid anatomical structure can be identified.

The Stryker PROFESS™ system is indicated for intranasal and sinus surgery in which the use of computer-assisted surgery is appropriate and for which a CT image of the patient in accordance with the imaging protocol is available.
The Stryker PROFESS™ system supports the following surgical procedures:

- Endoscopic sinus surgery
- Intranasal procedures

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Eric A. Mann -S
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Section 5. 510(k) Summary

This section provides a summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

510(k) Owner:	Stryker Leibinger GmbH & Co. KG – Navigation Boetzinger Str. 41 D-79111 Freiburg, GERMANY (p) (269) 389-3434 (f) (269) 389-2375
Contact Person:	Becky Ditty Sr. Staff Regulatory Affairs Specialist 4100 E. Milham Ave Kalamazoo, MI 49002 becky.ditty@stryker.com
Registration No.:	8010177
Trade Name:	Stryker PROFESS™ System
Common Name:	Navigation System
Classification Name:	Ear, Nose, and Throat Stereotaxic Instrument
Regulation Number:	882.4560
Product Code:	PGW
Device Description:	The PROFESS™ System, consisting of a computer platform, software and sterile single-use accessories, is designed to enable image guided surgery in intranasal and sinus surgery. Specifically, the system tracks and displays to the surgeon the intraoperative location of navigated surgical instruments, for example suction tools, relative to a CT image. The PROFESS™ System is based on the use of live video images captured by the miniature video camera mounted on the PROFESS™ Navigated Surgical Instruments. The

captured images can be processed by the PROFESS™ Software for localization and tracking of the PROFESS™ Navigated Surgical Instrument relative to the PROFESS™ Patient Tracker as long as the PROFESS™ Patient Tracker is partially visible in the video image.

The following are the PROFESS™ System components:

- PROFESS™ Software
- PROFESS™ Navigated Surgical Instruments:
  - PROFESS™ Straight Suction
  - PROFESS™ Curved 70°Suction
  - PROFESS™ Curved 90° Suction
  - PROFESS™ Frontal Sinus Seeker
- PROFESS™ Registration Stickers
- PROFESS™ Patient Tracker
- PROFESS™ Adaptor Cable
- Computer platform containing an SPC-3 Workstation and IO-Tablet, one of:
  - Stryker ADAPT® Platform
  - Stryker Nav3® Platform
  - Stryker Nav3i™ Platform

Indications for Use: The Stryker PROFESS™ system is a navigation surgical software module that, when used with a specific Stryker computer workstation, is intended as an intraoperative guidance system to enable intranasal and sinus computer assisted surgery. The system tracks and displays the intraoperative location of navigated surgical instruments relative to a CT image. The system can be used for intra-operative guidance where a reference to a rigid anatomical structure can be identified.

The Stryker PROFESS™ system is indicated for intranasal and sinus surgery in which the use of computer assisted surgery is appropriate and for which a CT image of the patient in accordance with the imaging protocol is available.

The Stryker PROFESS™ system supports the following surgical procedures:

- Endoscopic sinus surgery

- Intranasal procedures

Predicate Devices: The PROFESS™ System has the same intended use and technological characteristics as the predicate devices shown in the following tables:

Predicate Device	510(k) Number	Clearance Date	Predicate Substantial Equivalence Characteristic
Stryker Navigation System – ENT Module	K002732	10/01/2000	Navigated Surgical Instruments
Stryker Navigation System – Cranial Module	K062640	12/14/2006	Application Software Patient Reference Localizer Registration Accessories
Stryker NAV3i Platform	K130874	09/27/2013	Computer Platform

TABLE 5-1 PREDICATE DEVICES

Feature	Subject Device	Predicate Devices
Indications for Use	The Stryker PROFESS™ system is a navigation surgical software module that, when used with a specific Stryker computer workstation, is intended as an intraoperative guidance system to enable intranasal and sinus computer-assisted surgery. The system tracks and displays the intraoperative location of navigated surgical instruments relative to a CT image. The system can be used for intraoperative guidance where a reference to a rigid anatomical structure can be identified. The Stryker PROFESS™ system is indicated for intranasal and sinus surgery in which the use of computer-assisted surgery is appropriate and for which a CT image of the patient in accordance with the imaging protocol is available. The Stryker PROFESS™ system supports the following surgical procedures: ▪ Endoscopic sinus surgery ▪ Intranasal procedures	**K002732, Stryker Navigation System – ENT Module** The Stryker Navigation System – ENT Module is intended as a planning and intraoperative guidance system to enable open or percutaneous image guided surgery. The system is indicated for any medical condition in which the use of image guided surgery may be appropriate, and where a reference to a rigid anatomical structure can be identified relative to medical images. The ENT Module is also indicated for intranasal or sinus use. **K062640, Stryker Navigation System – Cranial Module (iNtellect)** The Stryker Navigation System – Cranial Module is intended as a planning and intraoperative guidance system to enable open or percutaneous computer assisted surgery. The system is indicated for any medical condition in which the use of computer assisted planning and surgery may be appropriate. The system can be used for intra-operative guidance where a reference to a rigid anatomical structure can be identified. The system should be operated only by trained personnel such as surgeons and clinic staff. The Cranial Navigation system supports, but is not limited to, the following surgical procedures: ENT/Neuro Procedures ▪ Endoscopic Sinus Surgery (ESS) ▪ Intranasal procedures ▪ Ear implant procedures Neuro Procedures ▪ Cranial biopsies ▪ Puncture of abscesses ▪ Craniotomies ▪ Craniectomies ▪ Resection of tumors and other lesions ▪ Removal of foreign objects ▪ Skull base procedures ▪ Transnasal neurosurgical procedures ▪ Transphenoidal pituitary surgery ▪ Shunt placement, including pediatric shunt placement ▪ Placement of electrodes for recording, stimulation and lesion generation ▪ Craniofacial procedures ▪ Skull reconstruction procedures ▪ Orbital cavity reconstruction procedures ▪ Placement of patient specific implants

Feature	Subject Device	Predicate Devices
Indications for Use (continued)		**K130874, Stryker NAV3i Platform** The NAV3i platform is a computer workstation that, when used with specific Stryker Navigation surgical software, displays patient specific images and/or patient specific anatomical landmark information and tracks the position and movement of surgical instruments in relation to a target anatomical site on a patient. The clinical setting and target population for the NAV3i Platform is that of a patient undergoing a surgical procedure using stereotactic techniques. **Equivalent**
Components	• PROFESS™ Software • PROFESS™ Navigated Surgical Instruments • PROFESS™ Registration • Stickers • PROFESS™ Patient Tracker • PROFESS™ Adaptor Cable • Computer platform, one of: o Stryker ADAPT® Platform o Stryker Nav3® Platform o Stryker Nav3i™ Platform	**K002732, Stryker Navigation System – ENT Module** • ENT Software • Navigated Surgical Instruments • Instrument Battery • Patient Tracking System • Computer Platform: o Stryker Navigation System I – Cart **K062640, Stryker Navigation System – Cranial Module** • iNtellect Software • Navigated Surgical Instruments • Instrument Battery • Patient Registration Mask • Computer Platform, one of: o Stryker Navigation System II – Cart o Stryker eNlite **Equivalent**
Stryker ADAPT® Platform		
Workstation	Stryker PC-3 (SPC-3)	**K130874, Stryker NAV3i Platform** Stryker PC-3 (SPC-3) **Equivalent**
Operating System	Windows XP	**K130874, Stryker NAV3i Platform** Windows XP **Equivalent**
User Interface	• IO-Tablet Touchscreen with virtual keyboard • Mouse	**K130874, Stryker NAV3i Platform** • IO-Tablet Touchscreen with virtual keyboard • Mouse **Equivalent**

Feature	Subject Device	Predicate Devices
Main Monitor	24”	**K130874, Stryker NAV3i Platform** 32” **Equivalent**
Main Monitor Position	Fixed position facing surgical field	**K130874, Stryker NAV3i Platform** Mounted on articulated arm for flexible positioning **Equivalent**
Localizer	N/A	**K130874, Stryker NAV3i Platform** Infrared optical localizer Navigation System II Camera **Equivalent**
Interfaces	• USB • CD/DVD • Equipotentially Connector Additional interfaces, not used by PROFESS™ System: • LAN • BNC • S-Video	**K130874, Stryker NAV3i Platform** • USB • CD/DVD • Equipotentially Connector Additional interfaces, not used by PROFESS™ System: • LAN • BNC • S-Video • HDMI • DVI • VGA • FireWire • Microscope (Optional Accessory) **Equivalent**
RFID Reader	Deactivated by default, can be activated with an optional RFID Activation Kit	**K130874, Stryker NAV3i Platform** Deactivated by default, can be activated with an optional RFID Activation Kit **Equivalent**
WLAN Interface	Deactivated by default, cannot be activated by the user	**K130874, Stryker NAV3i Platform** Deactivated by default, can be activated with an optional WLAN Activation Kit **Equivalent**
Uninterruptible Power Supply	N/A	**K130874, Stryker NAV3i Platform** Yes **Equivalent**

Feature	Subject Device	Predicate Devices
Stryker Nav3® Platform		
Workstation	Stryker PC-3 (SPC-3)	**K130874, Stryker NAV3i Platform** Stryker PC-3 (SPC-3) **Equivalent**
Operating System	Windows XP	**K130874, Stryker NAV3i Platform** Windows XP **Equivalent**
User Interface	• IO-Tablet Touchscreen with virtual keyboard • Mouse	**K130874, Stryker NAV3i Platform** • IO-Tablet Touchscreen with virtual keyboard • Mouse **Equivalent**
Main Monitor	24”	**K130874, Stryker NAV3i Platform** 32” **Equivalent**
Main Monitor Position	Fixed position facing surgical field	**K130874, Stryker NAV3i Platform** Mounted on articulated arm for flexible positioning **Equivalent**
Localizer	Infrared optical localizer Navigation System II Camera	**K130874, Stryker NAV3i Platform** Infrared optical localizer Navigation System II Camera **Equivalent**
Interfaces	• USB • CD/DVD • Equipotentially Connector Additional interfaces, not used by PROFESS™ System: • LAN • BNC • S-Video	**K130874, Stryker NAV3i Platform** • USB • CD/DVD • Equipotentially Connector Additional interfaces, not used by PROFESS™ System: • LAN • BNC • S-Video • HDMI • DVI • VGA • FireWire • Microscope (Optional Accessory)

Feature	Subject Device	Predicate Devices
RFID Reader	Deactivated by default, can be activated with an optional RFID Activation Kit	**K130874, Stryker NAV3i Platform** Deactivated by default, can be activated with an optional RFID Activation Kit **Equivalent**
WLAN Interface	Deactivated by default, cannot be activated by the user	**K130874, Stryker NAV3i Platform** Deactivated by default, can be activated with an optional WLAN Activation Kit **Equivalent**
Uninterruptible Power Supply	N/A	**K130874, Stryker NAV3i Platform** Yes **Equivalent**
PROFESS™ Software		
Operating Principle	The PROFESS™ Software is installed on the computer platform. Images are imported in DICOM format. The software displays the anatomical images on a monitor facing the surgeon and provides the navigational information.	**K062640, Stryker Navigation System – Cranial Module** The iNtellect software is installed on the computer platform. Images are imported in DICOM format. The software displays the anatomical and functional images and planned items on a monitor facing the surgeon and provides the navigational information. **Equivalent**
Modes of Operation	• Data Import • System Setup • Registration • Navigation	**K062640, Stryker Navigation System – Cranial Module** • Data Import • Planning • System Setup • Registration • Navigation **Equivalent**
Control Mechanism	The software is controlled using: • Mouse • Touchscreen • Keyboard • via buttons on the sterile navigated surgical instruments	**K062640, Stryker Navigation System – Cranial Module** The software is controlled using: • Mouse • Keyboard • via buttons on the sterile navigated surgical instruments **Equivalent**
Localization and Tracking Technology	Video localization and tracking technology: A miniature video camera mounted on the PROFESS™ Navigated Surgical Instruments captures live video images which can be processed by the PROFESS™ Software for localization and tracking of the PROFESS™ Navigated Surgical Instrument relative to the PROFESS™ Patient Tracker	**K062640, Stryker Navigation System – Cranial Module** Infrared optical active sensing technology: Infrared light emitted by diodes placed in a known fashion on navigated surgical instruments is sensed by a camera array (Navigation Camera) on the computer platform, thus allowing for computation of the spatial information. **Equivalent**

Feature	Subject Device	Predicate Devices
System Accuracy Statement	Within the nasal cavities the system has a mean accuracy of 2 mm	**K062640, Stryker Navigation System – Cranial Module** Within the camera working space, the system has a mean accuracy of 2 mm for translation and 2° for rotation **Equivalent**
Supported Image Modalities	• CT	**K062640, Stryker Navigation System – Cranial Module** • CT • CTA • MR • MRA • fMRI • PET • SPECT **Equivalent**
Scanner Interfaces	• CD/DVD • USB	**K062640, Stryker Navigation System – Cranial Module** • CD/DVD • USB • Network connectivity • Magneto Optical Disk **Equivalent**
Recommended CT Imaging Protocol	• No oblique angle of locator/survey lines • No gantry tilt • Slice thickness – 1 x 1 or 1.25 x 1.25 mm best; 2.0 mm maximum • Scan contiguous, no gap, no overlapping • Pixel/Matrix MUST be square – 256 x 256 minimum; 512 x 512 maximum • FOV– Smallest to include patient's external soft tissue, particularly tip of nose and top of head • Scan inferior to superior from hard palate to and including top of vertex • Axial, soft tissue algorithm, never bone, helical/spiral acceptable • Patient supine • Patients head in true anatomical position with tip of nose most anterior	**K062640, Stryker Navigation System – Cranial Module** • Contiguous, non-overlapping slices. • Constant slice thickness. Thinnest possible slice thickness (1-2 mm best, 3 mm maximum acceptable) • Use higher resolution imaging to increase accuracy, e.g., 512 x 512 pixels. • Pixels must be square, use the same matrix and pixel size for all images. • No relative shifts or rotations of the images in one set, no gantry tilt. • Use smallest field of view to fully encompass the region of interest with suitable resolution. Include the • For mask registration, the scan has to encompass the entire nose, including the tip of the nose. • Scan from the hard palate to the skull vertex. **Equivalent**
Registration	• Surface matching using video tracking of the PROFESS™ Registration Stickers to capture the patient's skin surface • Anatomical landmark matching	**K062640, Stryker Navigation System – Cranial Module** • Surface matching using Infrared optical active sensing of the Patient Registration Mask to capture the patient's skin surface • Surface matching using pointer to digitize a minimum of 32 distributed arbitrary points on the patient's skin • Anatomical landmark matching **Equivalent**

Feature	Subject Device	Predicate Devices
Display of Tip Location in Navigation Mode	Multiplanar reconstruction with sagittal, coronal and axial views with superimposed cross-hairs to indicate the intraoperative tip location of the PROFESS™ Navigated Surgical Instrument	**K062640, Stryker Navigation System – Cranial Module** • Multiplanar reconstruction with sagittal, coronal and axial views with superimposed cross-hairs to indicate the intraoperative tip location of the navigated surgical instruments. • 3D views with superimposed cross-hairs to indicate the intraoperative tip location of the navigated surgical instruments and a surface or volumetric reconstruction along with a rendered representation of the tools at the actual location. **Equivalent**
Check for Sustained Accuracy Intra-operatively	• Navigated surgical instrument's tip geometry check on initialization of instrument. • Intra-operative interactive landmark test.	**K062640, Stryker Navigation System – Cranial Module** • Navigated surgical instrument's tip geometry check on initialization of instrument. • Intra-operative interactive landmark test. **Equivalent**
PROFESS™ Navigated Surgical Instruments		
Power Supply	5V power supply from USB port on computer platform via PROFESS™ Adaptor Cable	**K002732, Stryker Navigation System – ENT Module** 3V power supply from Instrument Battery **Equivalent**
Communication with Computer Platform	Via PROFESS™ Adaptor Cable using USB 2.0 protocol	**K002732, Stryker Navigation System – ENT Module** Wireless infra-red communication using proprietary protocol **Equivalent**
Number of Buttons for Control of Software from the Sterile Field	1 Button	**K002732, Stryker Navigation System – ENT Module** 3 Buttons **Equivalent**
Calibration	Calibrated at the manufacturer's site	**K002732, Stryker Navigation System – ENT Module** Calibrated at the manufacturer's site **Equivalent**
Material (for body contacting parts)	AISI 301 or AISI 304 Stainless Steel	**K002732, Stryker Navigation System – ENT Module** AISI 301 or AISI 304 Stainless Steel **Equivalent**
Sterilization Method	Ethylene Oxide (EO) sterilized	**K002732, Stryker Navigation System – ENT Module** • Navigated Surgical Instruments: Steam Sterilized • Instrument Battery: Ethylene Oxide (EO) Sterilized or Gamma Sterilized **Equivalent**

Feature	Subject Device	Predicate Devices
Single Use vs. Re-Usable	Sterile, Single-use Only	**K002732, Stryker Navigation System – ENT Module** • Navigated Surgical Instruments: Sterile Re-usable • Instrument Battery: Sterile, Single-use Only **Equivalent**
PROFESS™ Patient Tracker		
Patient Reference Localizer	The PROFESS™ Patient Tracker is the patient reference localizer. The PROFESS™ Patient Tracker contacts the patient on the bridge of the nose (nasion) and the two outer ear canals. The patient tracker is elastic to fit different head sizes. Additionally, the position of the ear-pins can be adjusted for very small or large head sizes.	**K062640, Stryker Navigation System – Cranial Module** The Patient Registration Mask is used as the patient reference localizer. The Patient Registration Mask is applied to the patient's skin. **Equivalent**
Material (for body contacting parts)	• ABS Resin • Thermoplastic Polymer (TPE)	**K062640, Stryker Navigation System – Cranial Module** • 3M™ Hypoallergenic pressure sensitive acrylate based adhesive **Equivalent**
Single-Use vs. Re-Usable	Single-use	**K062640, Stryker Navigation System – Cranial Module** Single-use **Equivalent**
Sterilization Method	Ethylene Oxide (EO) sterilized	**K062640, Stryker Navigation System – Cranial Module** Ethylene Oxide (EO) sterilized **Equivalent**
PROFESS™ Registration Stickers		
Registration Accessories	The PROFESS™ Registration Stickers are used to define where skin points are sampled for surface matching	**K062640, Stryker Navigation System – Cranial Module** The Patient Registration Mask is used to define where skin points are sampled for surface matching **Equivalent**
Material (for body contacting parts)	3M™ Hypoallergenic pressure sensitive acrylate based adhesive	**K062640, Stryker Navigation System – Cranial Module** 3M™ Hypoallergenic pressure sensitive acrylate based adhesive **Equivalent**
Single-Use vs. Re-Usable	Single-use	**K062640, Stryker Navigation System – Cranial Module** Single-use **Equivalent**
Sterilization Method	Ethylene Oxide (EO) sterilized	**K062640, Stryker Navigation System – Cranial Module** Ethylene Oxide (EO) sterilized **Equivalent**

TABLE 5-2 COMPARISON TABLE

Substantial Equivalence (SE) Rational:

The conclusions drawn from the nonclinical tests demonstrate that the Stryker PROFESS™ System performs substantially equivalent to the predicate devices. The differences in the indications for use, technological characteristics and performance characteristics do not raise new questions of safety and effectiveness. Consequently, the Stryker PROFESS™ System is substantially equivalent to the predicate devices. According to the comparison based on the requirements of 21 CFR 807.87 and the information provided herein, it is concluded that the Stryker PROFESS™ System is substantially equivalent to the predicate devices with respect to its intended use, technological characteristics and performance characteristics.

Non-Clinical Testing:

Verification and validation activities have been conducted to provide assurance that the device meets the performance requirements under its intended use conditions.

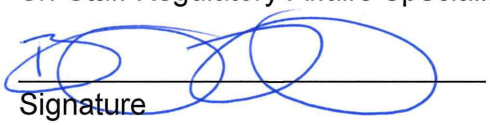
Test	Description
Accuracy	Verified the accuracy of ± 2 mm according to ASTM F2554:2010 and in phantom and cadaver tests
Accelerated Ageing Testing	Verified functionality of all single-use, sterile components and integrity of all packaging after accelerated ageing
Biocompatibility	Verified the biocompatibility of all patient contact materials according to ISO 10993-1:2009 and FDA draft guidance on the use of ISO 10993-1, April 23, 2013
Electrical Safety	Verified conformance to ANSI/AAMI ES 60601-1:2006-02.
Electromagnetic Compatibility	Verified conformance to IEC 60601-1-2: 2007-03, CISPR 11 Group 1, Class A requirements as well as additional testing to verify compatibility with RFID devices operating in the 125 - 134 kHz frequency band.
General Requirements and Performance	Verified all components against their design specifications
Safety	Verified the effectiveness of all risk controls determined in the device risk analysis

Test	Description
Shipping	Verified functionality of all components after simulated shipping conditions
Software	Verification and validation according to IEC 62304:2006 and FDA guidance on general principles of software validation, June 9, 1997
Sterilization	Validated the EO sterilization process for all single-use, sterile components according to ISO 11135-1:2007 to a sterility assurance level (SAL) of 10-6 and verified that the EO and ECH residuals are within the limits defined in ISO 10993-7:2008.
Product Validation	Validated the product with users in cadaver labs. Verified compatibility with conventional operative technique and other devices used in intranasal or sinus surgery.

Clinical Testing: No clinical testing has been conducted.

Conclusion: The results of the nonclinical tests demonstrate that the Stryker PROFESS™ System performs as safely and effectively as the legally marketed predicate devices. According to the comparison based on the requirements of 21 CFR 807.87 and the information provided herein, it is concluded that the Stryker PROFESS™ System is substantially equivalent to the predicate devices with respect to its intended use, technological characteristics and performance characteristics

Submitted by: Becky Ditty
Sr. Staff Regulatory Affairs Specialist



Signature

Date Submitted: June 10, 2014